approach that primarily addresses fire deaths caused by smoldering ignition sources using bench scale models to one that relies on the use of fire barriers to address fires started by multiple types of ignition sources (including smoking materials) by limiting fire growth similar to the performance requirements in 16 CFR 1633. Staff has encountered problems with controlling standard materials (foam, fabric, barriers) when used in bench scale tests with a smoldering ignition source. Staff became concerned with the NPR approach when correlation of fire performance between bench scale tests and full scale chair tests—when tested for smoldering ignition—was not validated. Chairs tested with fire barriers consistently performed better than non-barrier chairs in open flame testing. In assessing the potential new strategy, CPSC staff is seeking information on the following questions:

1. Can fire barriers used by the mattress industry be used in upholstered furniture applications?
2. What modifications to mattress fire barriers, if any, are necessary to make them effective in upholstered furniture?
3. What technologies (Fire retardant (FR) chemicals, specialty fibers/fabrics without FR chemicals, inherently fire resistant materials, etc.) do fire barrier manufacturers use to achieve improved fire performance?
4. Do fire barrier manufacturers use FR chemicals to achieve improved fire performance? If so, are the FR chemicals covalently bonded to the barrier? What is the risk of human exposure from the specific FR chemicals used? What exposure testing and data exists for the specific FR chemicals used? Is the product that uses an FR chemical based fire barrier labeled to indicate use of such FR chemicals within it?
5. What, if any, FR chemicals are used in mattress or other fire barrier technologies?
6. What are the cost considerations for using fire barriers? How does furniture manufacturing and assembling change with a fire barrier?
7. Given the variety of ignition sources involved in furniture fires, which ignition sources resulting in fatalities would fire barriers be effective in addressing the fatalities?
8. What fire safety technologies from commercial furniture can be applied to residential furniture?
9. What fire safety technologies from other industries (*e.g.,* marine, aviation) can be applied to residential furniture?
10. For fire barrier materials that do not use FR chemical treatments, what materials are used and what human exposure data exist for those materials?

Dated: March 15, 2013.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2013–06372 Filed 3–19–13; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211

[Docket No. FDA–2011–N–0920]

RIN 0910–AG36

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA or we) is correcting a proposed rule that published in the **Federal Register** of January 16, 2013. That proposed rule would amend our regulation for current good manufacturing practice in manufacturing, packing, or holding human food (CGMPs) to modernize it and to add requirements for domestic and foreign facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish and implement hazard analysis and risk-based preventive controls for human food. That proposed rule also would revise certain definitions in our current regulation for registration of food facilities to clarify the scope of the exemption from registration requirements provided by the FD&C Act for ''farms.'' We proposed these actions as part of our announced initiative to revisit the CGMPs since they were last revised in 1986 and to implement new statutory provisions in the FD&C Act. The document published with several typographical errors, stylistic errors (such as incorrect indentation of bulleted paragraphs and a gap in the sequential numbering of tables), and a mistake in the date of a reference. The document also published with an Appendix in which all references are numbered incorrectly. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2166.

SUPPLEMENTARY INFORMATION: FDA is correcting the January 16, 2013 (78 FR 3646), proposed rule entitled ''Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.'' The document published with several typographical errors, stylistic errors (such as incorrect indentation of bulleted paragraphs and a gap in the sequential numbering of tables), and a mistake in the date of a reference. We note that there are a total of 10 numbered tables in the preamble. These tables are numbered as follows: Table 1 (page 3675), table 2 (page 3679), table 3 (page 3680), table 4 (page 3682), table 5 (page 3687), table 6 (page 3692), table 8 (page 3714), table 9 (page 3717), table 10 (page 3718), and table 11 (page 3728). There is no table numbered ''Table 7''. We are not changing the table numbers to adjust the gap between tables 6 and 8 because the cross-references within the document to tables 8, 9, 10, and 11 are all correct, and because the gap between tables 6 and 8 is a stylistic error that does not affect the substantive content of the document. We apologize for any confusion. The document also published with an Appendix in which all references are numbered incorrectly. This document corrects those errors.

In FR Doc. 2013–00125, beginning on page 3646, in the **Federal Register** of Wednesday, January 16, 2013, we are making the following corrections:

1. On page 3650, in the first column, in the first full paragraph, in the last sentence, ''Pub. L. 111–533'' is corrected to read ''Public Law 111–353''.

2. On page 3717, in the second column of ''Table 9—Proposed Revisions for Consistency of Terms,'' in the first entry, ''the phrase ''food-production purposes (i.e., manufacturing, processing, packing, and holding) to consistently use the same group of terms in proposed part 117'' is corrected by closing the quotation after the parenthetical phrase to read ''the phrase ''food-production purposes (i.e., manufacturing, processing, packing, and holding)'' to consistently use the same group of terms in proposed part 117''.

3. On page 3728, in the first column of ''Table 11—Potential Revisions to Establish Requirements in Place of Current Guidance,'' in the fifth entry, ''§ 117.40(a)(1)'' is corrected to read ''§ 117.40(a)(3)''.

4. On page 3728, in the second column of ''Table 11—Potential Revisions to Establish Requirements in Place of Current Guidance,'' in the fifth entry, the word ''must'' in ''All

equipment must be so installed'' is corrected to be italicized and read ''must'' for emphasis.

5. On page 3735, in the first column, in line 25 under ''Radiological Hazards,'' the section reference ''III.D.2.e'' is corrected to read ''II.D.2.e''.

6. On page 3765, in the second column, the ninth, tenth, eleventh, and twelfth bulleted paragraphs and in the third column, the first and second bulleted paragraphs are corrected by doubly indenting them to show that these bulleted paragraphs are all examples relevant to the eighth bulleted paragraph on specifying the frequency of sample collection.

7. On page 3780, in the third column, in line 15, ''requirements of part 110'' is corrected to read ''requirements of part 117''.

8. On page 3794, in the third column, in the third paragraph, the date ''2012'' in reference 194 is corrected to read ''2013''.

9. In proposed § 117.135(d)(3)(iv), on page 3806, in the third column, ''records review in accordance with § 117.150(d)(5)(i)'' is corrected to read ''records review in accordance with § 117.150(d)(2)(i)''.

10. On pages 3812 through 3821, the references to the Appendix are numbered incorrectly. For the convenience of the reader, a corrected Appendix, with the correct reference numbers, is printed below.

The Appendix has been revised to read as follows:

Appendix

Although the proposed rule that is the subject of this document does not include specific codified language regarding environmental monitoring or finished product testing, we believe that these regimes can play a critical role in a modern food safety system. In sections XII.J.2 and XII.J.3 of the preamble of this document, we request comment on when and how these types of testing are an appropriate means of implementing the statutory directives set out in section 418 of the FD&C Act. In this Appendix, we provide background material on these testing measures.

I. The Role of Testing as a Verification Measure in a Modern Food Safety System

A. Verification of Preventive Controls

The safety of food is principally ensured by the effective implementation of scientifically valid preventive control measures throughout the food chain (Ref. 1) (Ref. 2). Prevention of hazards in food is much more effective than trying to differentiate safe from unsafe food using testing. Although testing is rarely considered a control measure, it plays a very important role in ensuring the safety of food. An important purpose of testing is to verify that control measures, including those related to suppliers and those verified through environmental monitoring, are controlling the hazard (Ref. 3) (Ref. 4). Testing is used in conjunction with other verification measures in the food safety system, such as audits of suppliers, observations of whether activities are being conducted according to the food safety plan, and reviewing records to determine whether process controls are meeting specified limits for parameters established in the food safety plan. Although testing may be conducted for biological, chemical, physical or radiological hazards, the most common testing is for microbiological hazards. Thus, much of the testing described below focuses on microbial testing, but many of the issues discussed apply to testing for other hazards as well. We focus more of our discussion below on verification testing of the environment because of the increasing recognition of the benefits of such testing in identifying conditions that could result in environmental pathogens contaminating food; thus such verification testing is important in preventing contamination in food, whereas verification testing of raw materials, ingredients, and finished products is used to detect contamination that has already occurred.

As discussed in sections I.C, I.E, and I.F of this Appendix, microbial testing may include:

- Testing raw materials and ingredients to verify that suppliers have significantly minimized or prevented hazards reasonably likely to occur in the raw materials and ingredients;
- Testing the environment to verify that sanitation controls have significantly minimized or prevented the potential for environmental pathogens to contaminate RTE food; and
- Testing finished product to verify that preventive controls have significantly minimized or prevented hazards reasonably likely to occur in the food.

Each type of testing provides information applicable to managing hazards in foods, depending on the food and process. For example, a dry blending operation, e.g., for spices and seasonings, often verifies its supplier controls by testing incoming ingredients before use (as discussed in section I.C of this Appendix) and periodically sampling and testing finished products. If all the ingredients being blended had been treated to adequately reduce hazards such as *Salmonella* spp., a dry blending operation generally does less testing to verify supplier controls than if this were not the case. (We use the term ''adequately reduce'' (which is a term used in some of our guidance documents) (Ref. 5) (Ref. 6) to mean the same as ''significantly minimize or prevent'' as described in section 418 of the FD&C Act or ''prevent, eliminate or reduce to an acceptable level'' as used in our seafood and juice HACCP regulations. All these terms mean to reduce a hazard to an extent that it is not reasonably likely to cause illness or injury.) A dry blending operation generally does not test incoming ingredients if the facility treats the blended materials to ensure adequate reduction of pathogens but sometimes tests finished product to verify preventive controls have been effective. A dry blending operation also sometimes uses environmental monitoring to verify that sanitation controls to significantly minimize or prevent the potential for environmental pathogens to contaminate the blended materials have been effective.

For acidified canned vegetables in which a lethal process is delivered in the final package, microbial testing of incoming ingredients and of finished product provides little benefit as a verification activity (although it would be used in process validation); however, facilities producing such products sometimes conduct periodic testing of incoming ingredients for pesticides as an appropriate supplier verification activity.

B. Scientifically Valid Sampling and Testing

Consistent with our previous discussion of the term ''scientifically valid'' in the proposed rule to establish CGMP requirements for dietary ingredients and dietary supplements (68 FR 12158 at 12198), we use the term ''scientifically valid'' with respect to testing to mean using an approach to both sampling and testing that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research. A scientifically valid analytical method is one that is based on scientific data or results published in, for example, scientific journals, references, text books, or proprietary research (68 FR 12158 at 12198). Sampling and testing used for verification in a food safety system must be scientifically valid if they are to provide assurance that preventive controls are effective.

C. Verification Testing of Raw Materials and Ingredients

Raw materials and ingredients are often tested as part of a supplier approval and verification program, as one of the verification activities when a preventive control that is adequate to significantly minimize or prevent the hazard is not applied at the receiving facility. The utility and frequency of raw material and ingredient testing for verification of supplier controls depend on many factors, including:

- The hazard and its association with the raw material or ingredient;
- The likelihood that the consumer would become ill if the hazard were present in the raw material or ingredient;
- How that raw material or ingredient will be used by the receiving facility (e.g., the effect of processing on the hazard); and
- The potential for contamination of the facility's environment with the hazard in the raw material or ingredient.

Testing a raw material or ingredient occurs more frequently when there is a history of the hazard in the raw material or ingredient, e.g., from a specific supplier or from the country of origin. Once a facility has developed a relationship with a supplier and there is a history of tests negative for the hazard, the frequency is often reduced.

Testing a raw material or ingredient is more useful, and a facility generally tests a raw material or ingredient more frequently, when the raw material or ingredient contains a hazard for which there is a reasonable

probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals. However, when a hazard that the receiving facility has identified as reasonably likely to occur in a raw material or ingredient is one for which the receiving facility has preventive controls that significantly minimize or prevent the hazard, testing generally is less frequent. An exception to this general paradigm is when the process control depends on the amount of the hazard present in the raw material or ingredient (e.g., when the process control is effective at eliminating 100 microorganisms per gram of ingredient, but not 1000 microorganisms per gram of ingredient) and there is a need to verify that the hazard is not present in amounts that would render the process control ineffective. A receiving facility often finds that testing of raw materials or ingredients is most useful, and generally tests more frequently, when the receiving facility does not have a process that would significantly minimize the hazard and is relying on preventive controls earlier in the supply chain to significantly minimize or prevent the hazard in the raw material or ingredient, as in a bagged salad facility or a dry-mix operation producing, for example, spice blends or trail mix. In such situations, the testing is conducted to verify the preventive controls used to ensure that hazards in the raw material or ingredient have been significantly minimized or prevented.

The frequency of the testing conducted by a facility generally depends in part on the likelihood and severity of illness to the consumer if the hazard were present, the ability of supplier controls to significantly minimize or prevent the hazard in the raw material or ingredient, the practicality of testing to detect the hazard, and other factors. For example, a facility generally tests a raw material or ingredient more frequently from a supplier that does not have a kill step for *Salmonella* spp. in shelled nutmeats compared to a supplier that steam treats the nuts to kill *Salmonella* spp. As another example, if a facility tests a raw material or ingredient as part of its food safety program for salad greens, the facility is more likely to test more frequently for *E. coli* O157:H7 than for other Shiga-toxin producing *E. coli* (pathogenic *E. coli* that produce the same toxin as *E. coli* O157:H7 but are less likely to cause severe illness (Ref. 7)), based on both the severity of the illness to the consumer and practical problems with testing fresh produce for pathogenic strains of Shiga-toxin producing *E. coli*. Where a raw material or ingredient could introduce an environmental pathogen such as *Salmonella* spp. or *L. monocytogenes* to the facility (e.g., raw nuts or soy powder for *Salmonella* spp.; chopped celery to be used in a salad for *L. monocytogenes*), a facility generally tests the raw material or ingredient more frequently to verify that supplier controls for the raw material or ingredient minimize to the extent possible the potential for a contaminated raw material or ingredient to introduce the environmental pathogen to the facility's environment.

As discussed in section I.F of this Appendix, there are limitations to testing food. Thus, as with other testing, raw material or ingredient testing is rarely the sole basis for making a determination on the safety of a raw material or ingredient.

D. Verification of Sanitation Controls to Significantly Minimize or Prevent the Potential for an Environmental Pathogen to Contaminate Food

1. Environmental Pathogens in Food

As discussed in section II.D of the preamble of this document, food can become contaminated with pathogenic microorganisms at many different steps in the farm-to-table continuum. Any time a food is exposed to the environment during a manufacturing, processing, packing, or holding activity, there is the potential for the food to be contaminated with pathogenic microorganisms. As discussed in section X.B of the preamble of this document, proposed § 117.3 would define the term ''environmental pathogen'' to mean a microorganism that is of public health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment. The environmental pathogens most frequently involved in the contamination of foods leading to foodborne illness are *Salmonella* spp. and *L. monocytogenes*.

2. *Salmonella* spp. as an Environmental Pathogen

We discuss *Salmonella* spp. in section II.D.2.a of the preamble of this document. *Salmonella* has been isolated from a variety of foods and it can get into food by a variety of mechanisms (see section II.D of the preamble of this document). Our focus here is on *Salmonella* contamination from the environment (discussed further in section I.D.2 of this Appendix), particularly as a hazard associated with low-moisture foods (Ref. 8) (Ref. 9). Low-moisture foods include cereal, peanuts, nuts, nut butters (including peanut butter), spices, dried herbs, milk powder, chocolate and many other foods. Although *Salmonella* outbreaks from low-moisture foods are less common than from foods such as eggs and produce, several such outbreaks in the last decade have involved hundreds of illnesses (Ref. 8). The low-moisture foods causing outbreaks included cereal, raw almonds, dried snacks, spices, and peanut butter (Ref. 8) (Ref. 10). Chocolate also has been a source of outbreaks from *Salmonella* spp., although none in the U.S. in recent years (Ref. 8). Dried dairy products, such as milk and whey, also present a risk of contamination with *Salmonella* spp. from the environment (Ref. 11). A review of FDA recall data from 1970 to 2003 showed there were 21 recalls of spices and herbs contaminated with *Salmonella* spp. (Ref. 12). Almost half of the 86 primary RFR entries reported in the first RFR Annual Report due to finding *Salmonella* spp. were from low-moisture foods (Ref. 13).

3. *Listeria monocytogenes* as an Environmental Pathogen

We discuss *L. monocytogenes* in section II.D.2.a of the preamble of this document. As discussed in that section, the FDA/FSIS Lm RA shows that the risk of illness from *L. monocytogenes* increases with the number of cells ingested and that there is greater risk of illness from RTE foods that support growth of *L. monocytogenes* than from those that do not (Ref. 14). A key finding of the risk assessment released by FAO in 2004 was that the models developed predict that nearly all cases of listeriosis result from the consumption of high numbers of the pathogen (Ref. 15). Refrigerated foods present a greater risk from *L. monocytogenes* because some refrigerated foods that support growth may be held for an extended period of time, thus increasing the risk if *L. monocytogenes* is present in a food. Growth of *L. monocytogenes* does not occur if the food is frozen, but the organism may survive. If a frozen food contaminated with *L. monocytogenes* is thawed and held at temperatures that support growth, e.g., under refrigeration, the risk of illness from *L. monocytogenes* in that food increases. As discussed in section II.D.1 of the preamble of this document, contamination of RTE food with *L. monocytogenes* from the environment is common and, thus, targeted preventive controls to significantly minimize or prevent *L. monocytogenes* contamination of RTE foods are warranted.

4. Environmental Pathogens in the Plant Environment

Environmental pathogens may be introduced into a facility through raw materials or ingredients, people, or objects (Ref. 8) (Ref. 9) (Ref. 16) (Ref. 17) (Ref. 18). Once in the facility, environmental pathogens can be a source of contamination of food. Environmental pathogens may be transient strains or resident strains (Ref. 8) (Ref. 9) (Ref. 16). Transient strains are environmental pathogens that contaminate a site in the facility where they can be eliminated by normal cleaning and sanitizing (Ref. 16). Transient strains tend to vary over time within a facility, e.g., they will be found in different areas and the specific strain will differ. Resident strains are environmental pathogens that contaminate a site in the facility that is difficult to clean and sanitize with normal cleaning and sanitizing procedures and, thus, these strains become established in what is referred to as a ''niche'' or harborage site (Ref. 8) (Ref. 9) (Ref. 16) (Ref. 17) (Ref. 18) (Ref. 19). The finding of the same specific strain multiple times in a facility often indicates a resident strain.

If a harborage site contains nutrients (i.e., food) and water and is exposed to a temperature that falls within the growth range of the environmental pathogen, the pathogen can multiply, which increases the chance that it will be transferred to other sites (including food-contact surfaces) and to food. Transfer can occur by people (e.g., if a person touches the contaminated site and then touches other objects, or tracks the pathogen from the contamination site to other sites on shoes), by equipment (e.g., if the pathogen is picked up by the wheels of a cart or forklift and is transferred to other locations), by water (e.g., water that contacts the harborage site is splashed onto other areas, including equipment, or aerosols containing the pathogen transfer it to other areas) or by air (dissemination of contaminated dust particles by air handling systems) (Ref. 8) (Ref. 9) (Ref. 19) (Ref. 17).

Such transfer mechanisms from harborage sites can result in intermittent contamination of food-contact surfaces and food over long periods of time, often with the same strain of the pathogen (Ref. 8) (Ref. 16) (Ref. 19) (Ref. 20).

5. Contamination of Food With *Salmonella* spp. From the Plant Environment

As discussed immediately below, the available data and information associate insanitary conditions in food facilities with contamination of a number of foods with the environmental pathogen *Salmonella* spp. Such contamination has led to recalls and to outbreaks of foodborne illness.

In 1998, a breakfast cereal product was implicated in an outbreak, due to *Salmonella* Agona, that caused 409 illnesses and one death in 23 states (Ref. 20) (Ref. 21) (Ref. 22). During the outbreak investigation, *Salmonella* was isolated from various locations in the plant, including the floor, processing equipment, and the exhaust system of the implicated processing line (Ref. 20). In 2008, the same *Salmonella* Agona strain was again implicated in an outbreak linked to a similar cereal product from the same manufacturing facility (Ref. 23). In the 2008 outbreak, the same strain was isolated from patients, cereal and the plant environment (Ref. 23).

In 2006–2007, a commercial brand peanut butter contaminated with *Salmonella* Tennessee caused 715 illnesses and 129 hospitalizations (Ref. 24). FDA isolated *Salmonella* Tennessee from 13 unopened jars of peanut butter with production dates ranging from August 2006 to January 2007 and from two plant environmental samples (Ref. 25).

During the years 2008 through 2010, there were three large recalls of foods containing ingredients contaminated with *Salmonella* spp. where FDA's investigation identified insanitary conditions at the facility that manufactured the ingredient and detected *Salmonella* spp. in the plant environment (Ref. 26) (Ref. 27) (Ref. 28) (Ref. 29) (Ref. 30) (Ref. 31) (Ref. 32) (Ref. 33) (Ref. 34). In 2008–2009, an outbreak was linked to *Salmonella* Typhimurium in peanut butter and peanut paste (Ref. 28) (Ref. 29) (Ref. 32). This outbreak resulted in an estimated 714 illnesses, 166 hospitalizations, and 9 deaths (Ref. 29). Implicated foods included contaminated peanut butter consumed at institutional settings and crackers made with the contaminated peanut butter as an ingredient (Ref. 28) (Ref. 29). Inspections conducted by FDA at the two implicated ingredient manufacturing facilities (which shared ingredients) revealed lack of controls to prevent product contamination from pests, from an insanitary air-circulation system, from insanitary food-contact surfaces, and from the processing environment (Ref. 26) (Ref. 30) (Ref. 31). Several strains of *Salmonella* spp. were found in multiple products and in the plant environment (Ref. 30). This outbreak led to the recall of more than 3900 products containing peanut-derived ingredients (Ref. 35).

In 2009, USDA detected *Salmonella* spp. in a powdered dairy shake and FDA began an investigation of the suppliers of ingredients used to manufacture the product. The inspection of the supplier of one of the ingredients uncovered insanitary conditions that resulted in the recall of multiple ingredients manufactured by that supplier, including instant nonfat dried milk and whey proteins, produced over a 2-year period (Ref. 33). During its investigation of the supplier's facility, FDA identified several strains of *Salmonella* spp. on food-contact and non-food-contact surfaces and in other areas of the plant environment, as well as a number of sanitation deficiencies (Ref. 34).

In 2010, FDA received a report through the RFR of *Salmonella* contamination of hydrolyzed vegetable proteins that a company purchased as an ingredient. Both the company that submitted the report and FDA found multiple *Salmonella*-positive samples collected from the plant environment, including food-contact surfaces. FDA found numerous sanitation deficiencies during its inspection of the production facility. There were no reports of illness associated with the contamination, but multiple product recalls resulted (Ref. 27).

6. Contamination of Food with *L. monocytogenes* From the Plant Environment

As discussed immediately below, the available data and information associate insanitary conditions in food facilities with contamination of a number of foods with the environmental pathogen *L. monocytogenes.* Such contamination has led to recalls and to outbreaks of foodborne illness.

Between October 2008 and March 2009, eight cases of listeriosis from five states were linked to Mexican-style cheese that was likely contaminated post-pasteurization (Ref. 36). The outbreak strain was isolated from product and from a vat gasket in a post-pasteurization section of the processing line.

In October 2010, the Texas Department of State Health Services ordered a fresh-cut produce facility to stop processing after laboratory tests of chopped celery indicated the presence of *L. monocytogenes* (Ref. 37). The testing was done as part of an investigation of 10 cases of listeriosis, six of which were linked to chopped celery from the facility. Texas Department of State Health Services and FDA inspectors found sanitation deficiencies at the plant (Ref. 37) (Ref. 38) and suggested that the *L. monocytogenes* in the chopped celery may have contaminated other produce. FDA laboratory testing found *L. monocytogenes* in multiple locations in the plant environment, including on food-contact surfaces; the DNA fingerprint of the *L. monocytogenes* in the FDA samples matched the DNA fingerprint of the clinical cases reported by the Texas Department of State Health Services (Ref. 39).

In 2011, an outbreak of listeriosis from cantaloupes was attributed to insanitary conditions at a facility that washed, packed, cooled, and stored intact cantaloupes (Ref. 40) (Ref. 41). The outbreak appears to have occurred due to a combination of factors, including pooled water on the floor of the facility (which was also difficult to clean), poorly designed equipment (not easily cleaned and sanitized) that was previously used for a different commodity, no pre-cool step, a truck parked near the packing area that had visited a cattle operation, and possible low level contamination from the growing/harvesting operation (Ref. 40).

There have been several outbreaks in which meat or poultry products produced in FSIS-inspected establishments were contaminated with *L. monocytogenes* from the plant environment (Ref. 42), and much of our understanding of sources of *L. monocytogenes* in the plant environment, as well as appropriate ways to control this organism, has come from the efforts of FSIS and the meat and poultry industry to control this hazard in FSIS-inspected establishments (Ref. 18). For example, harborage sites such as hollow rollers, rubber seals, close-fitting metal-to-metal spaces in equipment such as slicers, and on-off switches of equipment were identified in meat and poultry establishments. The increased risk of contamination resulting from construction, and the importance of control of traffic and water in the RTE area also became widely known as a result of investigations at meat and poultry establishments (Ref. 17) (Ref. 18).

Outbreaks of listeriosis resulting from environmental contamination have also occurred in other countries. For example, an outbreak of listeriosis in Finland in 1999 was associated with butter (Ref. 43). The outbreak strain was isolated from the manufacturing facility, including from the packaging machine and the floor (Ref. 43). An outbreak of listeriosis in 2009 in Austria and Germany was associated with acid curd cheese; the outbreak strain was found in the production facility (Ref. 44).

Many foods without a known association with illnesses have been recalled due to the presence of *L. monocytogenes* (Ref. 45) (Ref. 46) (Ref. 47) (Ref. 48). There is also an extensive body of literature on isolation of *L. monocytogenes* in the food processing environment. Information on the environment as a source of *Listeria* has been available for many years. For example, in a 1989 study involving 6 different types of food plants (frozen food, fluid dairy, cheese, ice cream, potato processing, and dry food), drains, floors, standing water, food residues, and food-contact surfaces were found to be positive (Ref. 49). No finished foods were tested, but the authors concluded that food production environments could be the source of contamination for foods that have received listericidal treatments and that measures should be taken to prevent survival and growth of these organisms in food environments (Ref. 49).

Listeria testing in 62 dairy facilities during 1987–1988 (including facilities producing fluid milk, frozen product, butter, processed cheese, natural cheese and dry products) found *Listeria* in a variety of locations, including packaging equipment, conveyors, coolers, drains and floors (Ref. 50). *Listeria* was detected more frequently in wet locations, including drains, conveyors and floors (Ref. 50). Pritchard and co-workers also examined 21 dairy processing environments for *Listeria* and found 80 of 378 sites positive for *Listeria* spp. (Ref. 51). Sites positive for *L. monocytogenes* included holding tanks, table tops, conveyor/chain systems, a milk filler and a brine pre-filter machine (Ref. 51).

The packaging machine was found to be the main problem with *L. monocytogenes*

that persisted in an ice cream plant in Finland for several years and occasionally contaminated finished product (Ref. 52). A volumetric doser was found to be the source of *L. monocytogenes* in sauces produced in a fresh sauce production plant in Italy (Ref. 53), and slicers and conveyor belts were found to contribute to contamination of sandwiches in a Swiss sandwich producing plant (Ref. 54). *L. monocytogenes* also has been found on tables, water hoses, air guns, floors, gloves, drains and a bread-feeding machine (Ref. 54).

Some of the available data and information about the potential presence of the environmental pathogen *L. monocytogenes* comes from studies conducted to detect the presence of *Listeria* spp. in lieu of *L. monocytogenes. Listeria* spp. are ''indicators'' of the potential presence of *L. monocytogenes.* (See section I.E of this Appendix for a discussion of indicator organisms). A study conducted over a 4-year time period on the prevalence of *L. monocytogenes* on produce and in the plant environment in a large produce processing plant in Poland demonstrated that the indicator organism *Listeria* spp., and the environmental pathogen *L. monocytogenes,* could be isolated from conveyor belts after blanching and from freezing tunnels (Ref. 55). Studies in a vegetable processing plant in Spain found the indicator organism *L. innocua* (commonly found when the species of *Listeria* spp. are determined) in frozen RTE vegetables and in the plant environment, e.g., washing tunnels, conveyor belts and floors (Ref. 56). *L. innocua* was more prevalent than *L. monocytogenes* in the frozen RTE vegetables and in the plant environment. In both of these examples, the presence of an ''indicator organism'' (either *Listeria* spp. or *L. innocua)* demonstrated that insanitary conditions existed that were conducive to the presence and harborage of *L. monocytogenes.*

E. Role of Environmental Monitoring in Verifying the Implementation and Effectiveness of Sanitation Controls in Significantly Minimizing or Preventing the Potential for an Environmental Pathogen to Contaminate Food

1. Purpose of Environmental Monitoring

Appropriate sanitation controls can minimize the presence of environmental pathogens in the plant and the transfer of environmental pathogens to food-contact surfaces and to food (Ref. 16). The purpose of monitoring for environmental pathogens in facilities where food is manufactured, processed, packed or held is to verify the implementation and effectiveness of sanitation controls intended to significantly minimize or prevent the potential for an environmental pathogen to contaminate food. In so doing, environmental monitoring can find sources of environmental pathogens that remain in the facility after routine cleaning and sanitizing (particularly strains that may have become established in the facility as resident strains) so that the environmental pathogens can be eliminated by appropriate corrective actions (e.g., intensified cleaning and sanitizing, sometimes involving equipment disassembly). Pritchard et al. noted that daily cleaning and sanitizing appeared to be effective in eliminating transient contaminants from equipment and concluded that greater emphasis needs to be placed on cleaning and sanitizing the plant environment (Ref. 51). A robust environmental monitoring program for environmental pathogens can detect these strains and enables the facility to eliminate them from the environment which can prevent contamination of food with these pathogens and, thus, prevent foodborne illnesses (Ref. 57) (Ref. 17) (Ref. 18) (Ref. 58) (Ref. 59). In the situations described in sections I.D.5 and I.D.6 of this Appendix, such a program for the environmental pathogens *Salmonella* spp. and *L. monocytogenes* might have allowed the facility to detect a problem before product contamination occurred, thereby preventing an outbreak, recall, or both, or minimizing the amount of product affected by a recall. Studies of environmental pathogens have clearly demonstrated that environmental monitoring can identify the presence of situations that can lead to contamination of food and allow actions to be taken to prevent such contamination (Ref. 51) (Ref. 60).

2. Indicator Organisms

The term ''indicator organism'' can have different meanings, depending on the purpose of using an indicator organism. As discussed in the scientific literature, the term ''indicator organism'' means a microorganism or group of microorganisms that is indicative that (1) a food has been exposed to conditions that pose an increased risk for contamination of the food with a pathogen or (2) a food has been exposed to conditions under which a pathogen can increase in numbers (Ref. 61). This definition in the scientific literature is consistent with a definition of indicator organism established by NACMCF as one that indicates a state or condition and an index organism as one for which the concentration or frequency correlates with the concentration or frequency of another microorganism of concern (Ref. 62). FDA considers the NACMCF definition of an indicator organism to be an appropriate working definition for the purpose of this document.

The use of ''indicator organisms'' as a verification of hygiene measures in facilities is common practice (Ref. 63). For example, it is common practice to use the presence of generic (nonpathogenic) *E. coli* in a food processing plant as an indication of whether food was prepared, packed, or held under insanitary conditions, without considering whether the insanitary conditions reflect a specific pathogen, such as *E. coli* O157:H7 or *Salmonella* spp. However, such use of an indicator organism is distinct from the use of indicator organisms as discussed in the remainder of this document—i.e., for the specific purpose of monitoring for the presence of environmental pathogens.

Environmental monitoring for environmental pathogens can be conducted by testing for the specific pathogenic microorganism (e.g., *Salmonella* spp.) or by testing for an ''indicator organism.'' The presence of an indicator organism indicates conditions in which the environmental pathogen may be present. An organism is useful as an indicator organism if there is sufficient association of conditions that could result in the presence of the indicator organism and conditions that could result in the pathogen such that there can be confidence that the pathogen would not be present if the indicator is not present. Attributes that provide scientific support for use of an indicator organism in lieu of a specific pathogen include:

- Similar survival and growth characteristics;
- A shared common source for both organisms; and
- A direct relationship between the state or condition that contributes to the presence of pathogen and the indicator organism (Ref. 62).

The presence of an indicator organism in the plant environment, including on a food-contact surface, does not necessarily mean that an environmental pathogen is in the plant or in a food produced using that food-contact surface—the indicator may be present but the pathogen may be absent. Pritchard et al., in their study on the presence of *Listeria* in dairy plant environments, concluded that, because the level of contamination was higher in environmental samples than in equipment samples, environmental contamination with *Listeria* does not necessarily translate into contamination of equipment in the plant (Ref. 51).

Typically, a facility that finds an indicator organism during environmental monitoring conducts microbial testing of surrounding surfaces and areas to determine the potential source of the contamination, cleans and sanitizes the contaminated surfaces and areas, and conducts additional microbial testing to determine whether the contamination has been eliminated. If the indicator organism is found on retest, the facility generally takes more aggressive corrective actions (e.g., more intensified cleaning and sanitizing, including dismantling equipment, scrubbing surfaces, and heat-treating equipment parts) (Ref. 17). In general, whether a facility takes subsequent steps to determine an indicator organism detected on a food-contact surface is actually the environmental pathogen depends, in part, on the risk of foodborne illness if the food being produced on a food-contact surface that has tested positive for an indicator organism were to be contaminated. For example, the risk of listeriosis is greater if the food supports growth of *L. monocytogenes.* In some cases, a facility simply assumes that a food produced using a food-contact surface that is contaminated with an indicator organism is contaminated with the environmental pathogen and takes corrective action to either reprocess it or divert it to a use that would not present a food safety concern.

3. Environmental Monitoring for L. monocytogenes and the Use of an Indicator Organism

Tests for the indicator organism *Listeria* spp. detect multiple species of *Listeria,* including the pathogen *L. monocytogenes.* There is Federal precedent for the use of *Listeria* spp. as an appropriate indicator organism for *L. monocytogenes.* FSIS has established regulations requiring FSIS-regulated establishments that produce RTE

meat or poultry products exposed to the processing environment after a lethality procedure (e.g., cooking) to prevent product adulteration by *L. monocytogenes.*

FSIS has issued guidelines (FSIS Compliance Guideline for Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products) (hereinafter the FSIS *Listeria* Compliance Guideline) to help FSIS-regulated establishments that produce RTE meat or poultry products exposed to the processing environment after a lethality procedure comply with the requirements of 9 CFR part 430 (Ref. 64). Under the FSIS *Listeria* Compliance Guideline, FSIS-regulated establishments may establish an environmental monitoring program for *Listeria* spp. rather than for the pathogen, *L. monocytogenes.*

In general, under the FSIS *Listeria* Compliance Guideline, an FSIS-regulated establishment that receives a positive test result for an indicator organism on a food-contact surface:

- Takes corrective action (i.e., intensify the cleaning and sanitizing of the affected food-contact surface);
- Retests the affected food-contact surface; and
- Takes additional corrective action (intensified each time the test is positive for the indicator organism) and conducts additional testing until the affected food-contact surface is negative for the indicator organism.

Some segments of the food industry subject to regulation by FDA have adopted the principles, described in the FSIS *Listeria* Compliance Guideline, for corrective actions after a finding of *Listeria* spp. on food-contact surfaces in the plant. For example, in response to a request for comments on a draft guidance document directed to control of *L. monocytogenes* in refrigerated or frozen ready-to-eat foods, we received letters describing programs similar to the program in the FSIS *Listeria* Compliance Guideline, using *Listeria* spp. as an indicator organism during environmental monitoring for *L. monocytogenes* (Ref. 65) (Ref. 66) (Ref. 67) (Ref. 68). In addition, as discussed in section II.A.1 of the preamble of this document, a key finding of the CGMP Working Group Report was the importance of updating CGMP requirements to require a written environmental pathogen control program for food processors that produce RTE foods that support the growth of *L. monocytogenes.* Written comments from the food industry supported such a control program (Ref. 69). Thus, the importance of controlling *L. monocytogenes* in the environment of RTE food production facilities and using environmental monitoring to detect the presence of *L. monocytogenes* or *Listeria* spp. (as an indicator organism for *L. monocytogenes*) has been well-established.

FDA's current thinking is that *Listeria* spp. is an appropriate indicator organism for *L. monocytogenes,* because tests for *Listeria* spp. will detect multiple species of *Listeria,* including *L. monocytogenes,* and because the available information supports a conclusion that modern sanitation programs, which incorporate environmental monitoring for *Listeria* spp., have public health benefits.

4. Environmental Monitoring for *Salmonella* spp. and the Use of an Indicator Organism

Salmonella spp. is a member of the family Enterobacteriaceae, and thus there is some relationship between the presence of *Salmonella* spp. and the presence of Enterobacteriaceae. There are few studies that have investigated the use of organisms such as Enterobacteriaceae or other members of the family Enterobacteriaceae, such as *E. coli,* to serve as an indicator organism for *Salmonella* spp. in the environment. The European Food Safety Agency (EFSA) evaluated whether environmental monitoring for Enterobacteriaceae as an indicator organism for *Salmonella* spp. (or for *Cronobacter* spp.) could be useful. Although EFSA's focus was on the utility of Enterobacteriaceae as an indicator organism in the production of a single product—i.e., powdered infant formula—their analysis may be relevant to the utility of Enterobacteriaceae as an indicator organism in other dried foods. EFSA concluded that, although there are insufficient data to establish a correlation between the presence of Enterobacteriaceae and *Salmonella* spp. in powdered infant formula because *Salmonella* spp. is so rarely present, monitoring for Enterobacteriaceae in the product environment can be used to confirm the application of GMPs (Ref. 70). ICMSF also considered the utility of environmental monitoring for Enterobacteriaceae as an indicator organism for *Salmonella* spp. ICMSF indicates that, for powdered infant formula manufacturing, low levels of Enterobacteriaceae do not guarantee the absence of *Salmonella* spp. (Ref. 71) and recommends testing directly for the pathogen, as well as for Enterobacteriaceae. FDA agrees with EFSA and ICMSF that there are insufficient data to establish a correlation between the presence of Enterobacteriaceae and *Salmonella* spp. during the production of powdered infant formula; FDA is not aware of any information supporting the use of an indicator organism for the purpose of environmental monitoring for *Salmonella* spp. during the production of other foods, particularly dried foods.

ICMSF recommends testing for *Salmonella* spp. in the environment for a number of other products, e.g., baked dough products (Ref. 72), dry spices receiving a kill step (Ref. 73), dried cereal products (Ref. 74), nuts (Ref. 75), cocoa powder, chocolate and confectionary (Ref. 76), and dried dairy products (Ref. 77). For most of these products ICMSF also recommends testing the environment for Enterobacteriaceae as a hygiene indicator, but not in lieu of the environmental pathogen *Salmonella* spp. Likewise, food industry guidance for low-moisture foods recommends testing for *Salmonella* spp. in the environment (Ref. 59). FDA's current thinking is that there is no currently available indicator organism for *Salmonella* spp. We request data, information, and other comment bearing on whether there is a currently available indicator organism for *Salmonella* spp. that could be used for environmental monitoring.

5. Environmental Monitoring Procedures

The procedures associated with an environmental monitoring program generally include the collection of environmental samples at locations within the facility and testing the samples for the presence of an environmental pathogen or indicator organism. One approach to defining sampling locations is to divide the facility into zones based on the risk with respect to contamination of product. A common industry practice is to use four zones (Ref. 16) (Ref. 59):

- Zone 1 consists of food-contact surfaces;
- Zone 2 consists of non-food-contact surfaces in close proximity to food and food-contact surfaces;
- Zone 3 consists of more remote non-food-contact surfaces that are in the process area and could lead to contamination of zones 1 and 2; and
- Zone 4 consists of non-food-contact surfaces, outside of the processing area, from which environmental pathogens can be introduced into the processing environment.

Generally the number of samples and frequency of testing is higher in zones 1 and 2 because of the greater risk of food contamination if the environmental pathogen is detected in these zones. Information on appropriate locations for sampling within these zones can be found in the literature (Ref. 11) (Ref. 17) (Ref. 50) (Ref. 51) (Ref. 59). Facilities should become familiar with locations in which environmental pathogens have been found in other facilities and use this information in selecting sites to sample.

Examples of appropriate food-contact surfaces that could be monitored include hoppers, bins, conveyors, tables, slicers, blenders, knives and scrapers. Testing food-contact surfaces for *Listeria* spp. is a commonly recommended verification measure for facilities producing refrigerated RTE foods (Ref. 57) (Ref. 16) (Ref. 17). Although some literature suggests that routine environmental monitoring for *Salmonella* spp. in low-moisture food environments would not normally target food-contact surfaces (Ref. 59), the data (discussed in the preamble of this document) available from investigations of food facilities following outbreaks, recalls, or reports to the RFR warrant including food-contact surfaces in a routine environmental testing program for *Salmonella* spp. However, a routine environmental monitoring program for *Salmonella* spp. may not contain the same level of food-contact surface testing (including the frequency of testing and number of samples collected) as a routine environmental monitoring program for *Listeria,* because the same benefits may not be achieved. For example:

- *L. monocytogenes* is usually the environmental pathogen of concern for most wet RTE food production environments. It is important to sample areas where the organisms are likely to be present in relatively high numbers. *L. monocytogenes* frequently establishes itself in a harborage site on equipment and grows (increases in number) there, where both food and moisture are available. *L. monocytogenes* organisms work their way out of the harborage site during production and contaminate food.
- *Salmonella* spp. is usually the environmental pathogen of concern for most dry (e.g., low-moisture) RTE food

environments. Equipment used in the production of dry products is rarely wet and, thus, there is no moisture to allow growth of *Salmonella* spp. As a result, *Salmonella* harborage sites are less likely to be found on equipment and are more likely to be found in the environment in locations where food particles lodge and escape a dry cleaning process. When these locations get wet, the *Salmonella* spp. grows and contaminates other areas of the facility, eventually contaminating food-contact surfaces and food. Nevertheless, sampling food-contact surfaces (e.g., filler hoppers, conveyors, valves, sifter cuffs) can be useful, as can sampling residues such as sifter tailings and product scrapings.

Examples of appropriate non-food-contact surfaces that could be monitored include exteriors of equipment, equipment supports, control panels, door handles, floors, drains, refrigeration units, ducts, overhead structures, cleaning tools, motor housings and vacuum canisters. Standing water in production areas and areas that have become wet and then have dried are also appropriate places to monitor. Testing non-food-contact surfaces for *L. monocytogenes* or *Listeria* spp. is a commonly recommended verification measure for facilities producing refrigerated or frozen RTE foods (Ref. 57) (Ref. 16) (Ref. 17) and can detect *L. monocytogenes* that is brought into the plant by people or objects. Corrective actions can prevent transferring the organisms to a food-contact surface (where they can contaminate food) or from establishing a harborage that can serve as a source of contamination. Recommendations for routine environmental monitoring for *Salmonella* spp. in low moisture food environments generally target non-food-contact surfaces because equipment used in the production of low-moisture foods where *Salmonella* spp. is the environmental pathogen of concern does not have the moisture to allow *Salmonella* spp. to grow and, thus, sampling non-food-contact surfaces for *Salmonella* spp. may be more effective in finding the organism than sampling food-contact surfaces. Scrapings or residues that accumulate under or above equipment are more useful samples than sponges or swabs of food-contact surfaces (Ref. 76).

As discussed in section I.E.2 of this Appendix with respect to indicator organisms, a facility that finds an indicator organism or an environmental pathogen during environmental monitoring typically conducts microbial testing of surrounding surfaces and areas to determine the potential source of the contamination, cleans and sanitizes the contaminated surfaces and areas, and conducts additional microbial testing to determine whether the contamination has been eliminated. If the organism is found on retest, the facility generally takes more aggressive corrective actions (e.g., more intensified cleaning and sanitizing, including dismantling equipment, scrubbing surfaces, and heat-treating equipment parts) (Ref. 17).

The adequacy of a corrective action in response to environmental monitoring depends in part on the following factors related to the risk presented in a particular situation:

- Whether the environmental contamination is on a food-contact surface or a non-food-contact surface;
- The proximity of a contaminated non-food-contact surface to one or more food-contact surfaces;
- Whether there have been previous positives on the specific food-contact surface or non-food-contact surface or in the same area; and
- The environmental monitoring strategy for the type of food, and whether the food supports growth of the environmental pathogen (see the discussion of the relevance of whether a food supports the growth of an environmental pathogen in section I.D.4 of this Appendix).

If an environmental pathogen or an appropriate indicator organism (the test organism) is detected in the environment, corrective actions are taken to eliminate the organism, including finding a harborage site if one exists (Ref. 17) (Ref. 18) (Ref. 59). Otherwise, the presence of the environmental pathogen could result in contamination of food-contact surfaces or food. The presence of the indicator organism suggests that conditions exist in which the environmental pathogen may be present and could result in contamination of food-contact surfaces or food. Corrective actions are taken for every finding of an environmental pathogen or indicator organism in the environment to prevent contamination of food-contact surfaces or food.

Sampling and microbial testing from surfaces surrounding the area where the test organism was found are necessary to determine whether the test organism is more widely distributed than on the original surface where it was found and to help find the source of contamination if other sites are involved. Cleaning and sanitizing the contaminated surfaces and surrounding areas are necessary to eliminate the test organism that was found there. Additional sampling and microbial testing are necessary to determine the efficacy of cleaning and sanitizing. For example, detection of the test organism after cleaning and sanitizing indicates that the initial cleaning was not effective, and additional, more intensified cleaning and sanitizing, or other actions may be needed, including dismantling equipment, scrubbing surfaces, and heat-treating equipment parts (Ref. 17). Examples of additional corrective actions that could be taken include reinforcing employee hygiene practices and traffic patterns; repairing damaged floors; eliminating damp insulation, water leaks, and sources of standing water; replacing equipment parts that can become harborage sites (e.g., hollow conveyor rollers and equipment framework), and repairing roof leaks (Ref. 17) (Ref. 59). The types of corrective actions would depend on the type of food, the facility and the environmental pathogen.

The finding of a test organism on a food-contact surface usually represents transient contamination rather than a harborage site (Ref. 18). However, finding the test organism on multiple surfaces in the same area, or continuing to find the test organism after cleaning and sanitizing the surfaces where it was found, suggests a harborage site for the test organism. Mapping the location of contamination sites, whether the harborage site is on equipment or in the environment, can help locate the source of the harborage site or identify additional locations to sample (Ref. 59).

The types of facilities that may conduct environmental monitoring and that could implement corrective actions on finding the test organism in the facility are quite diverse, and include facilities producing low-moisture products such as cereals, chocolate and dried milk powders and facilities producing a variety of RTE refrigerated products such as deli salads, cheeses and bagged salads. The number of sites appropriate for testing and the applicable cleaning and sanitizing procedures would depend on the facility and the equipment.

Corrective actions may involve investigative procedures when the initial corrective actions have not been successful in eliminating the environmental pathogen or indicator organism. One example of an investigative procedure is taking samples from food-contact surfaces and/or product from the processing line at multiple times during the day while the equipment is operating and producing product (Ref. 17). Another example of an investigative procedure is conducting molecular strain typing such as pulsed-field gel electrophoresis (PFGE), ribotyping, or polymerase chain reaction (PCR) analysis to determine if particular strains are persistent in the environment (Ref. 19) (Ref. 78) (Ref. 54) (Ref. 52) (Ref. 53) (Ref. 79). Molecular strain typing can indicate that strains isolated at different points in time have the same molecular ''fingerprint,'' suggesting a common source, and perhaps a harborage site, that has not been detected based on the results of routine environmental monitoring (Ref. 52) (Ref. 53). Molecular strain typing can also be used when trying to determine if a specific ingredient is the source of contamination (Ref. 78).

If environmental monitoring identifies the presence of an environmental pathogen or appropriate indicator organism, the facility may conduct finished product testing. As discussed in section I.F of this Appendix, there are shortcomings for microbiological testing of food for process control purposes. Testing cannot ensure the absence of a hazard, particularly when the hazard is present at very low levels and is not uniformly distributed. If an environmental pathogen is detected on a food-contact surface, finished product testing would be appropriate only to confirm actual contamination or assess the extent of contamination, because negative findings from product testing could not adequately assure that the environmental pathogen is not present in food exposed to the food-contact surface. If a facility detects an environmental pathogen on a food-contact surface, the facility should presume that the environmental pathogen is in the food.

Finished product testing could be appropriate if an environmental pathogen is detected on a non-food-contact surface, such as on the exterior of equipment, on a floor or in a drain. The potential for food to be contaminated directly from contamination in

or on a non-food-contact surface is generally low, but transfer from non-food-contact surfaces to food-contact surfaces can occur. Finished product testing can provide useful information on the overall risk of a food when pathogens have been detected in the environment. In general, finished product testing is most appropriate when an indicator organism, rather than an environmental pathogen, is detected on a food-contact surface.

The results of finished product testing can be used in combination with the results of environmental monitoring and corrective actions to help ensure that the food released into commerce is not adulterated. For example, if a facility with an aggressive environmental monitoring program detects an indicator organism on a food-contact surface, it may use information such as the following in determining whether to release product into commerce:

- The number and location of positive sample findings, including from the original sampling and from additional/follow-up testing of areas surrounding the site of the original finding;
- The root cause analysis of the source of the contamination;
- Information on the efficacy of the facility's corrective actions (including the results of additional follow-up sampling);
- Information obtained from any finished product testing, taking into consideration the statistical confidence associated with the results.

F. The Role of Finished Product Testing in Verifying the Implementation and Effectiveness of Preventive Controls

The utility of finished product testing for verification depends on many factors that industry currently considers in determining whether finished product testing is an appropriate approach to reducing the risk that contaminated food would reach the consumer and cause foodborne illness. The first such consideration is the nature of the hazard and whether there is evidence of adverse health consequences from that hazard in the food being produced or in a similar food. If the hazard were to be present in the food, how likely is it that illness will occur and how serious would the consequences be? The more likely and severe the illness, the greater the frequency of conducting verification testing. For example, *Salmonella* spp. is a hazard that if consumed could cause serious illness, particularly in children and the elderly. In contrast, in situations where unlawful pesticide residues are considered reasonably likely to occur, the presence of a pesticide residue that is not approved for a specific commodity but that is within the tolerance approved for other commodities, while deemed unsafe as a matter of law, may not actually result in illness. Thus, a firm is more likely to conduct finished product testing to verify *Salmonella* spp. control than to verify control of pesticides.

Another consideration in determining whether finished product testing is appropriate is the intended consumer of the food. The greater the sensitivity of the intended consumer (as would be the case, for example, for a medical food provided to hospitalized adults), the greater the likelihood that finished product testing would be used as a verification activity.

Another consideration in determining whether finished product testing is appropriate is the impact of the food on the contaminant. For example, depending on the food, pathogens may survive in food, increase in number, or die off. Finished product testing generally is not conducted if pathogens that may be in a food would die off in a relatively short period of time (e.g., before the food reaches the consumer). For example, many salad dressings have antimicrobial properties, including low pH, high acidity, and preservatives, that are lethal for pathogens such as *Salmonella* spp. or *E. coli* O157:H7. If a facility has validated the lethality of the formulation of the salad dressing, the facility is unlikely to conduct finished product testing for pathogens such as *Salmonella* spp. or *E. coli* O157:H7, as this would not be an effective use of resources, particularly if proper formulation of the food is verified during production. In contrast, verification testing is more likely in food where pathogens can survive in a food, particularly where pathogens may grow in a food.

Another consideration in determining whether finished product testing is appropriate is the intended use of the food. For example, consumers cook many foods, e.g., dried pasta, cake mixes, and most frozen vegetables, thereby reducing pathogens. A facility should not rely on the consumer to eliminate hazards that can be prevented. However, there is little benefit in testing a food that is normally consumed following a step that can be relied on to inactivate the hazard. It is important to validate that the instructions provided to the consumer adequately reduce the pathogen of concern. It is also important to understand the customary use of the food, which may include uses that do not include the hazard reduction step. For example, dried soup mixes may be mixed with sour cream to make a dip, without the pathogen inactivation step that occurs when boiling the soup mix with water. If *Salmonella* spp. may be present in an ingredient for the soup mix, e.g., dried parsley or black pepper, and neither the supplier nor the facility treats the ingredient or the soup mix in a way that significantly reduces *Salmonella* spp., then finished product testing for *Salmonella* spp. would be warranted. Likewise, frozen peas and corn may be added to fresh salads, deli-type salads, or salsas without a pathogen inactivation step; finished product testing for *L. monocytogenes* could be warranted for these foods where this is a likely use.

Another consideration in determining whether finished product testing is appropriate is the type of controls the supplier has implemented to minimize the potential for the hazard to be present, e.g., whether the supplier uses a kill step for a pathogen or has other programs in place that will adequately reduce the hazard. A facility generally is more likely to conduct finished product testing when the supplier does not have a program that can ensure the hazard has been adequately reduced in the ingredient supplied. Another consideration is the verification procedures that are in place at the supplier and at the receiving facility. If the supplier has a well-executed control program, including a supplier approval and verification program that has been verified through audits to adequately reduce the hazard, the receiving facility performs periodic verification testing of the ingredient provided by the supplier, and the supplier has a good compliance history, the frequency of finished product verification testing by the receiving facility is low, particularly if the receiving facility has a process that further reduces the hazard. However, if the ingredient is associated with a hazard and the processes used by the supplier and the receiving facility will not significantly minimize it, or if a facility is using a new supplier, the frequency of finished product verification testing increases.

One of the most important considerations in determining whether finished product testing is appropriate is the effect of processing on the hazard. The frequency of finished product testing generally is low when a manufacturing process significantly minimize the hazard (e.g., a 5-log reduction of a pathogen) and procedures are in place to prevent recontamination after that process; the frequency of finished product testing increases when a manufacturing process does not significantly minimize the hazard (e.g., 1- or 2-log reduction of a pathogen). For example, testing is not common for bagged spinach that is irradiated to provide a 5-log reduction of *Salmonella* spp. and *E. coli* O157:H7; finished product verification testing would be more common if the only pathogen reduction step is washing the spinach leaves in chlorinated water. Likewise, FDA noted in the preamble to the juice HACCP regulation that it was not requiring end product verification testing for juice treated to achieve a 5-log reduction in a target pathogen because the post-treatment level of microorganisms would be too low to be detected using reasonable sampling and analytical methods (68 FR 6138 at 6174).

Another important consideration in determining whether finished product testing is appropriate is whether a hazard can be reintroduced into a food that has been treated to significantly minimize the hazard, either through exposure to the environment or by the addition of an ingredient after a treatment to significantly minimize a hazard. For example, verification testing is not common if a lethal treatment for a pathogen is given to food in its final package (such as a marinara sauce heated in the jar or hot-filled into the jar) but would be more common if food exposed to the environment, such as a cold gazpacho filled into a container. Likewise, verification testing generally is more frequent for foods given significant handling before packaging, regardless of whether they have previously received a treatment that would significantly minimize a hazard, if they will be consumed without a treatment lethal for pathogens that can be introduced during handling (e.g., *L. monocytogenes* or *Salmonella* spp. from the environment; pathogens such as *Staphylococcus aureus* or *Salmonella* spp. from food handlers). Verification testing also

would be more frequent if an ingredient that has potential to be contaminated with a pathogen is added to a food that was previously treated to significantly minimize a hazard (e.g., adding seasonings to chips or crackers after frying or baking) than if all ingredients are added before the treatment.

In assessing whether to conduct verification testing and determine the frequency of that testing, a facility generally considers the impact of all the preventive control measures applied in producing the food, because multiple control measures provide greater assurance that a hazard is being controlled. For example, the frequency or finished product verification testing generally could be lower for a food that is subject to supplier controls that include audits and certificates of analysis (COAs); that contains ingredients that have been subjected to ingredient testing; that is produced under well-implemented sanitation controls that are verified through a robust environmental monitoring program; and that is treated using a validated process that significantly minimizes the hazard than for a food that is not subject to all these controls. Finished product testing generally is more frequent during initial production cycles until there is an accumulation of historical data (e.g., finished product test results that are negative for the hazard) to confirm the adequacy of preventive controls. Once this history has been established, the frequency of testing generally is reduced to that needed to provide ongoing assurance that the preventive controls continue to be effective and to signal a possible loss of control, as discussed further immediately below.

There are well-known shortcomings of product testing, especially microbiological testing, for process control purposes, and it is generally recognized that testing cannot ensure the absence of a hazard, particularly when the hazard is present at very low levels and is not uniformly distributed (Ref. 61) (Ref. 80)). Moreover, the number of samples used for routine testing often is statistically inadequate to provide confidence in the safety of an individual lot in the absence of additional information about adherence to validated control measures. This is illustrated below for *Salmonella* spp.

FDA's Investigations Operations Manual (IOM) (Ref. 81) and Bacteriological Analytical Manual, BAM, (Ref. 82) provide sampling plans to determine the presence of *Salmonella* in processed foods intended for human consumption. The stringency of the sampling plan is based on the category of the food. Category III foods are those that would normally be subject to a process lethal to *Salmonella* spp. between the time of sampling and consumption (e.g., macaroni and noodle products, frozen and dried vegetables, frozen dinners, food chemicals). Category II foods are those that would not normally be subject to a process lethal to *Salmonella* spp. between the time of sampling and consumption (e.g., fluid milk products, cheeses, nut products, spices, chocolate, prepared salads, ready-to-eat sandwiches). Category I foods are Category II foods intended for consumption by the aged, the infirm, and infants (e.g., foods produced for a hospital). FDA takes 15 samples for Category III foods, 30 for Category II foods, and 60 for Category I foods and tests a 25 g subsample (analytical unit) from each sample. To reduce the analytical workload, the analytical units may be composited (Ref. 83), with the maximum size of a composite unit being 375 g (15 analytical units). This composite is tested in its entirety for *Salmonella* spp. The probability of detecting *Salmonella* spp. for various contamination rates under the three IOM Salmonella sampling plans is shown in Table 1. (Probability of Detecting *Salmonella*.)

TABLE 1—PROBABILITY OF DETECTING *Salmonella* SPP. IN LOTS AT VARIOUS CONTAMINATION RATES UNDER THE THREE DIFFERENT IOM *Salmonella* SAMPLING PLANS (LEFT) AND THE EXPECTED NUMBER OF POSITIVE COMPOSITE SAMPLES USING WEEKLY TESTING FOR 1 YEAR UNDER THE IOM *Salmonella* SAMPLING PLANS (RIGHT)

		Probability of detecting *Salmonella* spp. in a lot (percent)			Expected # of positive composites per year (weekly testing)		
Contamination Rate	CFU/g or CFU/kg	N=15*	n=30*	n=60*	n=15*	n=30*	n=60*
1 in 10	1/250g	79	96	>99	40	81	162
1 in 30	1/750g	40	64	87	20	41	82
1 in 100	1/2.5kg	14	26	45	7	15	29
1 in 300	1/7.5kg	4.9	10	18	2.5	5	10
1 in 1000	1/25kg	1.5	3	5.8	0.8	1.5	3
1 in 3000	1/75kg	0.5	1	2	0.3	0.5	1

* In the table, "n" is the number of subsamples (which are composited in groups of 15 for analysis).

The probability of detecting Salmonella spp. increases as the defect rate increases. For example, when 15 samples are tested, the probability of detecting Salmonella spp. is 14 percent when the contamination rate is 1 in 100, but 79 percent when the contamination rate is 1 in 10. For a given contamination rate, the probability of detecting Salmonella spp. increases with the number of samples tested. For example, at a contamination rate of 1 in 30, the probability of detecting Salmonella spp. increases from 40 percent if 15 samples are tested to 87 percent if 60 samples are tested.

Table 1 shows that it is clearly not feasible to attempt to identify low levels of contamination in an individual lot based on the IOM *Salmonella* sampling plan. If the contamination levels are high and 1 in 10 products are contaminated, then Salmonella spp. would be detected in the lot greater than 99 percent, 96 percent, and 79 percent of the time using Category I, II, and III testing, respectively. If the frequency of contaminated units is reduced to 1 in 300, then the contaminated lot would only be detected 18 percent, 10 percent, and 4.9 percent of the time using Category I, II, and III testing, respectively. At a very low frequency of contamination (e.g., 1 in 1000) even with testing 60 samples the contaminated lot would be detected only about 6 percent of the time.

Periodic testing for trend analysis and statistical process control, however, does provide information to assess whether processes (or the food safety system) are under control over time. Data collected from multiple lots of product produced over days, months or years are used to establish a baseline for the level of control that can be attained under a functioning food safety system and to verify the system is in control or to indicate loss of control. In addition to showing the probability of detecting contamination in a lot of product for a given contamination rate, Table 1 also shows the value of periodic testing when contamination levels are low. Even though a product with 1 in 300 contaminated units is unlikely to be rejected when sampling a single lot at the Category III sampling schedule (i.e., 4.9 percent of the time), testing of finished products with this level of contamination on a weekly basis would be expected to find 2.5 positive composite samples per year. Similarly, if the background contamination rate is thought to be near 1 in 1000 but periodic testing using the Category III schedule has found 3 positives in the last year, then it seems clear that the actual frequency of contaminated units is closer to 1 in 300. Periodic testing according to the Category I *Salmonella* plan has the potential to detect situations where the contamination rates are as low as 1 in 1000. If 60 samples of a food are collected weekly, then 3,120 samples would be collected over the course of a year. Compositing these 3,120 samples into 375g analytical units would reduce the number of analytical tests to 208 (4 tests per week). If 30 samples are collected weekly, and composited, there would be 104 tests annually, or two each week. At the 1 in 1000 contamination rate there would be a greater than 95 percent confidence in seeing one or more positive tests during the year for testing composites from either 60 or 30 samples weekly. At higher rates of contamination, more positives would be detected.

There can be significant benefits to a facility testing finished products over time for process control. First, if a lot of product tests positive for a hazard, that lot of product can be disposed of such that the consumer is not exposed to the hazard (i.e., the product can be destroyed, reprocessed, or diverted to another use, as appropriate). If the testing involves enumeration of an indicator organism, it may even be possible to detect a trend toward loss of control before exceeding the criterion that separates acceptable from unacceptable. The process can be adjusted before there is a need to dispose of product. Second, the detection of loss of control, or potential loss of control, e.g., an unusual number of positives in a given period of time, allows a facility to evaluate and modify its processes, procedures, and food safety plan as appropriate to prevent loss of control in the future. In fact, the nature of the trends can provide information useful in determining the root cause of the problem (Ref. 61). A third benefit to ongoing verification testing is the accumulation of data that can help bracket any problem that occurs. For products in which there are large production runs without intervening sanitation cycles, this may provide data that can be used in conjunction with other information to limit the scope of a recall. A fourth benefit may be in detection of a problem associated with an ingredient supplier that results in changes to a supplier's processes, procedures, or food safety plan. For example, a positive in finished product due to routine verification testing was responsible for determining that hydrolyzed vegetable protein was contaminated with *Salmonella* spp., resulting in over 177 products being recalled (Ref. 84) and a recognition of the need for enhanced preventive controls for the production of this ingredient (Ref. 27). Industry commonly uses finished product testing to verify preventive controls used by the facility and by the facility's suppliers. Additionally, it is common for customers to require suppliers to conduct testing of products and ingredients being provided.

G. Metrics for Microbiological Risk Management

Recently there has been much attention paid to microbiological risk management metrics for verifying that food safety systems achieve a specified level of public health control, e.g., the Appropriate Level of Protection (ALOP), for microbial hazards. Microbiological risk management metrics are fully discussed in Annex II of the Codex ''Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)'' (Ref. 85). These metrics include traditional metrics such as microbiological criteria, process criteria, and product criteria and emerging metrics such as food safety objectives (FSO), performance objectives and performance criteria. Of particular relevance are performance objectives and performance criteria. A performance objective is the maximum frequency and/or concentration of a microbiological hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable (Ref. 86). A performance criterion is the effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a performance objective or an FSO (Ref. 86). FDA established a performance criterion (or performance standard) when we required that processors of juice products apply a control measure that will consistently produce, at a minimum, a 5-log reduction for the most resistant microorganism of public health significance (§ 120.24). Section 104 of FSMA (Performance Standards) requires the Secretary to determine the most significant foodborne contaminants and issue contaminant-specific and science-based guidance documents, including guidance documents regarding action levels, or regulations for products or product classes. The proposed rule that is the subject of this document would not establish criteria or metrics for verifying that preventive controls in food safety plans achieve a specified level of public health control in this proposed rule. However, FDA will give consideration to appropriate microbiological risk management metrics in the future.

II. The Role of Supplier Approval and Verification Programs in a Food Safety System

A food can become contaminated through the use of contaminated raw materials or ingredients. In the past several years, thousands of food products have been recalled as a result of contamination of raw materials or ingredients with pathogens such as *Salmonella* spp. and *E. coli* O157:H7. The ingredients included peanut-derived ingredients (Ref. 26) (Ref. 35), pistachio-derived ingredients (Ref. 87), instant nonfat dried milk, whey protein, fruit stabilizers (Ref. 88) (Ref. 89) (Ref. 33) and hydrolyzed vegetable protein (Ref. 90).

The incident involving *Salmonella* spp. in hydrolyzed vegetable protein illustrates the impact one supplier can have on the food industry (Ref. 13). A receiving facility (manufacturer) detected *Salmonella* spp. in verification testing of finished product. In determining the source of the contamination, the manufacturer detected *Salmonella* spp. in samples of a hydrolyzed vegetable protein ingredient and reported the finding through FDA's RFR. After FDA determined that the ingredient was a reportable food, FDA requested that the supplier notify the immediate subsequent recipients of the reported hydrolyzed vegetable protein ingredient. Over one thousand reportable food reports were submitted to FDA from numerous companies concerning the potentially contaminated hydrolyzed vegetable protein or products made with the hydrolyzed vegetable protein. The hydrolyzed vegetable protein recall involved at least eleven different commodity categories and 177 products, showing the magnitude of this contamination event originating from one supplier (Ref. 13).

FDA recently reviewed CGMP-related food recall information from 2008–2009 to assess potential root causes for the contamination events. We determined that 36.9 percent of the 960 Class I and Class II recalls were directly linked to lack of supplier controls (Ref. 91). The recent large recalls of foods containing contaminated or potentially contaminated ingredients have focused attention on supplier approval and verification programs intended to help a manufacturer/processor prevent the introduction of a contaminated raw material or other ingredient into another product (Ref. 35) (Ref. 84) (Ref. 89). The application of preventive approaches by the entire supply chain (including ingredient vendors, brokers and other suppliers and, ultimately, the manufacturer of a food product) is recognized as essential to effective food safety management (Ref. 92).

The development of a supplier approval and verification program is part of a preventive approach. Because many facilities acting as suppliers procure their raw materials and ingredients from other suppliers, there is often a chain of suppliers before a raw material or other ingredient reaches the manufacturer/processor. To ensure safe food and minimize the potential for contaminated food to reach the consumer, each supplier in the chain must implement preventive controls appropriate to the food and operation for hazards reasonably likely to occur in the raw material or other ingredient. A facility receiving raw materials or ingredients from a supplier must ensure that the supplier (or a supplier to the supplier) has implemented preventive controls to significantly minimize or prevent hazards that the receiving facility has identified as reasonably likely to occur in that raw material or other ingredient unless the receiving facility will itself control the identified hazard.

A supplier approval and verification program is a means of ensuring that raw materials and ingredients are procured from those suppliers that can meet company specifications and have appropriate programs in place, including those related to the safety of the raw materials and ingredients. A supplier approval program can ensure a methodical approach to identifying such suppliers. A supplier verification program provides initial and ongoing assurance that suppliers are complying with practices to achieve adequate control of hazards in raw materials or ingredients.

Supplier approval and verification is widely accepted in the domestic and international food safety community. The NACMCF HACCP guidelines describe Supplier Control as one of the common prerequisite programs for the safe production of food products and recommend that each facility should ensure that its suppliers have in place effective GMP and food safety programs (Ref. 1). The American Spice Trade Association advocates that spice manufacturers establish robust supplier prerequisite programs to evaluate and approve suppliers (Ref. 93). The Grocery Manufacturers Association's (GMA's) Food Supply Chain Handbook, developed for ingredient suppliers to the food industry, recommends that all suppliers in the food chain consider approval programs for their own suppliers; such supplier approval programs consist of a collection of appropriate programs, specifications,

policies, and procedures (Ref. 92). GMA recommends a number of verification activities that suppliers can take in its Food Supply Chain Handbook, including self-auditing, third-party auditing and product testing. GMA's handbook also references verification activities that a supplier's customers might take, including second-party audits (done by an employee of the customer) or third-party (independent) audits (conducted by persons who do not work for either the supplier or the customer). Codex specifies that no raw material or ingredient should be accepted by an establishment if it is known to contain parasites, undesirable microorganisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances which would not be reduced to an acceptable level by normal sorting and/or processing (Ref. 94). Codex also specifies that, where appropriate, specifications for raw materials should be identified and applied and that, where necessary, laboratory tests should be made to establish fitness for use (Ref. 94).

Supplier verification activities include auditing a supplier to ensure the supplier is complying with applicable food safety requirements, such as CGMP requirements of current part 110. Audit activities may include a range of activities, such as on-site examinations of establishments, review of records, review of quality assurance systems, and examination or laboratory testing of product samples (Ref. 95). Other supplier verification activities include conducting testing or requiring supplier COAs, review of food safety plans and records, or combinations of activities such as audits and periodic testing.

An increasing number of establishments that sell foods to the public, such as retailers and food service providers, are independently requiring, as a condition of doing business, that their suppliers, both foreign and domestic, become certified as meeting safety (as well as other) standards. In addition, domestic and foreign suppliers (such as producers, co-manufacturers, or re-packers) are increasingly looking to third-party certification programs to assist them in meeting U.S. regulatory requirements (Ref. 95). There are many established third-party certification programs designed for various reasons that are currently being used by industry. Many third party audit schemes used to assess the industry's food safety management systems incorporate requirements for manufacturers and processors to establish supplier approval programs.

The GFSI was established in 2000 to drive continuous improvement in food safety management systems to ensure confidence in the delivery of safe food to consumers worldwide. Their objectives include reducing risk by delivering equivalence and convergence between effective food safety management systems and managing cost in the global food system by eliminating redundancy and improving operational efficiency (Ref. 96). GFSI has developed a guidance document as a tool that fulfills the GFSI objectives of determining equivalency between food safety management systems (Ref. 96). The document is not a food safety standard, but rather specifies a process by which food safety schemes may gain recognition, the requirements to be put in place for a food safety scheme seeking recognition by GFSI, and the key elements for production of safe food or feed, or for service provision (e.g., contract sanitation services or food transportation) in relation to food safety (Ref. 96). This benchmark document has provisions relevant to supplier approval and verification programs. For example, it specifies that a food safety standard must require that the organization control purchasing processes to ensure that all externally sourced materials and services that have an effect on food safety conform to requirements. It also specifies that a food safety standard must require that the organization establish, implement, and maintain procedures for the evaluation, approval and continued monitoring of suppliers that have an effect on food safety. Thus, all current GFSI-recognized schemes require supplier controls to ensure that the raw materials and ingredients that have an impact on food safety conform to specified requirements. The GFSI guidance document also requires audit scheme owners to have a clearly defined and documented audit frequency program, which must ensure a minimum audit frequency of one audit per year of an organization's facility (Ref. 96).

Because GFSI is a document that outlines elements of a food safety management system for benchmarking a variety of standards, it does not have details about how facilities should comply with the elements. This type of information is found in the food safety schemes that are the basis for certification programs. For example, the Safe Quality Food (SQF) 2000 Code, a HACCP-based supplier assurance code for the food industry, specifies that raw materials and services that impact on finished product safety be supplied by an Approved Supplier. SQF 2000 specifies that the responsibility and methods for selecting, evaluating, approving and monitoring an Approved Supplier be documented and implemented, and that a register of Approved Suppliers and records of inspections and audits of Approved Suppliers be maintained. SQF 2000 requires that the Approved Supplier Program contain, among other items, agreed specifications; methods for granting Approved Supplier status; methods and frequency of monitoring Approved Suppliers; and details of certificates of analysis if required.

According to SQF, the monitoring of Approved Suppliers is to be based on the prior good performance of a supplier and the risk level of the raw materials supplied. The monitoring and assessment of Approved Suppliers can include:

- The inspection of raw materials received;
- The provision of certificates of analysis;
- Third party certification of an Approved Supplier; or
- The completion of 2nd party supplier audits.

III. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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Dated: March 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 112

[Docket No. FDA–2011–N–0921]

RIN 0910–AG35

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA or we) is correcting the preamble to a proposed rule that published in the **Federal Register** of January 16, 2013. That proposed rule would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. FDA proposed these standards as part of our implementation of the FDA Food Safety Modernization Act. The document published with several technical errors, including some errors in cross references, as well as several errors in reference numbers cited throughout the document. This document corrects those errors. We are also placing a corrected copy of the proposed rule in the docket.

FOR FURTHER INFORMATION CONTACT: Samir Assar, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1636.

SUPPLEMENTARY INFORMATION: FDA is correcting the preamble to the January 16, 2013 (78 FR 3504), proposed rule entitled ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.'' The document published with several technical errors, including some errors in cross references, as well as several errors in reference numbers cited throughout the document. This document corrects those errors. In addition, we inadvertently omitted the publication by ''Stine et al. (2005)'' from section X. References. We also omitted a reference for ''Todd et al. (2009)'' from section X. References. Therefore, we are correcting the References section to add new Reference 274 for ''Stine et al.'' and new Reference 275 for ''Todd et al.'' We are placing copies of both References 274 and 275 in the docket. We are also placing a corrected copy of the proposed rule in the docket (Ref. 1).

I. Corrections

In FR Doc. 2013–00123, beginning on page 3504, in the **Federal Register** of Wednesday, January 16, 2013, FDA is making the following corrections:

1. On page 3508, in the second column, in the first complete paragraph, in line 5, add the word ''uncommon'' at the end of the sentence directly in front of ''(Ref. 7).''

2. On page 3510, in the third column, the heading ''*B. Produce Safety Action Plan''* is corrected to read ''*C. Produce Safety Action Plan''.*

3. On page 3511, in the first column, the heading ''*C. Public Hearings''* is corrected to read ''*D. Public Hearings''.*

4. On page 3511, in the second column, the heading ''*D. Partnerships and Collaborations''* is corrected to read ''*E. Partnerships and Collaborations''.*

5. On page 3513, in the second column, the heading ''*E. Current Industry Practices''* is corrected to read ''*F. Current Industry Practices''.*

6. On page 3514, in the first column, in the third complete paragraph, in line 3, ''section II.D.'' is corrected to read ''section II.E''.

7. On page 3514, in the first column, the heading ''*F. 2010* ***Federal Register*** *Notice and Preliminary Stakeholder Comments''* is corrected to read ''*G. 2010* ***Federal Register*** *Notice and Preliminary Stakeholder Comments''.*